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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,258	09/16/2003	Jose Engelmayer	H0-P02652US1	2875

26271 7590 12/06/2006

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,258	ENGELMAYER ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *1-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-51 are pending.

Applicants' amendment filed September 26, 2006 is acknowledged. Applicant's response has been fully considered. Claims 15 and 16 have been amended. Claims 1-14 are non-elected inventions and withdrawn from consideration. Therefore, claims 15-51 are examined.

Claims 36-38 have been amended, however, the status of claims 36-38 are indicated as original, which is not correct. Appropriate correction is required.

Withdrawn Claim Objections

2. The previous objection to claims 36-38 is withdrawn in view of applicant's amendment to the claim, and applicants' response at page 8 in the amendment filed September 26, 2006.

Withdrawn Claim Rejections - 35 USC § 112

3. The previous rejection of claims 15-30 under 35 U. S. C. 112, second paragraph, regarding the outcome of the treatment, and claims 34-35, regarding which cytokine or chemikine being stimulated or inhibited, is withdrawn in view of applicant's amendment to the claim, and applicants' response at pages 8-9 in the amendment filed September 26, 2006.

Withdrawn Claim Rejections – 35 USC § 102

4. The previous rejection of claims 16-18, 21-23 and 26-51 under 35 U.S.C. 102(b) as being anticipated by Mita *et al.* (U. S. Patent 5,561,109), is withdrawn in view of applicant's amendment to the claim, and applicants' response at page 10 in the amendment filed September 26, 2006.

5. The previous rejection of claims 16-18, 21-23 and 26-51 under 35 U.S.C. 102(a) as being anticipated by Boyko *et al.* (WO 02/03910), is withdrawn in view of applicant's amendment to the claim, and applicants' response at page 10 in the amendment filed September 26, 2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 31-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 33-47, 49 and 51 are indefinite because the claims lack an essential step in the method of treating a wound, or enhancing the local or systemic immune system in a subject suffering from a wound. The omitted step is a therapeutically effective amount of a lactoferrin composition used in the treatment. Claims 34-47 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

8. Claims 31, 32, 48 and 50 are indefinite because the claim recites "an amount of a lactoferrin composition", it is not what amount of a lactoferrin composition is used, and what effect the amount of a lactoferrin composition would produce.

Response to Arguments

Applicant indicates the term "treating" or "treatment" are used herein refers to administering to a subject a therapeutically effective amount of a recombinant human lactoferrin composition so that the subject has an improvement in the disease. The improvement is any improvement or remediation of the symptoms. Thus, the outcome is encompassed within the meaning of treating (page 9 of the response).

Applicants' response has been considered, the argument is persuasive regarding the outcome of the treatment, thus the rejection is withdrawn. However, the claims do not recite the essential step of using a therapeutically effective amount of a human lactoferrin composition, thus, the rejection is maintained.

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 16-23, 26, 27, 29 and 31-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conneely *et al.* (US 2001/0016289 A1, filed February 25, 1999).

Conneely *et al.* disclose a method of treating a disorder such as duodenal or gastric ulcers resulting from infection by enteropathogens such as H. pylori using an effective amount of lactoferrin composition comprising lactoferrin and a pharmaceutically aceeptable carrier, where the lactoferrin can be administered orally, topically, intragastrically or parenterally either alone or in combination with antiacids or antibiotics (paragraphs [0002], [0038], [0071]-[0089]; claims 16-23, 26, 27, 29). Although Conneely *et al.* do not indicate administration of lactoferrin to the patient would supplement the local or systemic immune system, stimulate the production or inhibit of certain cytokines or chemokines, or inhibit the production of matrix metalloproteinases, the reference teaches the same method steps (i.e., administration of lactoferrin) as the claimed method, thus at the time of invention was made, it would have been obvious to one of ordinary skill in the art that the lactoferrin composition would produce these effects (claims 31-51).

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 15-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-14, 16, 18-22 and 35-

38 of copending Application No. 10/733,621 (based on the amended claims filed September 26, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15-51 in the instant application disclose a method of treating a wound, or enhancing the local or systemic immune system in a subject suffering from a wound by administering to the subject an effective amount of a lactoferrin composition comprising a lactoferrin and a pharmaceutically acceptable carrier. This is an obvious variation in view of claims 1, 3-14, 16, 18-22 and 35-38 in the copending application which disclose a method of treating a subject suffering from pain comprising the step of administering to the subject an effective amount of a lactoferrin composition, wherein the pain is associated with cancer or surgery; and the specification discloses the composition comprising a lactoferrin and a pharmaceutically acceptable carrier can be a gel composition comprising Carbopol. Both the claims of instant application and the claims of the copending application are directed to a method of treating wound or a patient having a pain from surgery by administering a lactoferrin composition, where a patient having a pain from surgery would be expected to have a wound. Thus, claims 15-51 in present application and claims 1, 3-14, 16, 18-22 and 35-38 in the copending application are obvious variations of a method of treating wound by administering a lactoferrin composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant did not respond to the rejection.

11. Claims 16-22, 26-30 and 50-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 14, 17-19,

26-32 and 38-40 of copending Application No. 10/728,521 (based on the amended claims filed September 26, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 16-22, 26-30 and 50-51 disclose a method of treating a wound other than ophthalmic wounds, or enhancing the local or systemic immune system in a subject suffering from a wound by administering to the subject an effective amount of a lactoferrin composition; and the specification indicates a lactoferrin composition can have an N-terminal lactoferrin variant such as N-terminal glycine deleted or substituted or a deletion, substitution, or combination thereof, of from 1 to 16 N-terminal amino acid residues and the N-terminal lactoferrin variant retains the same biological function as full length lactoferrin (paragraphs [0009] and [0048]), and the lactoferrin composition can decrease bacterial infection of the wound (paragraphs [0102]). This is an obvious variation in view of claims 1, 7, 14, 17-19, 26-32 and 38-40 in the copending application which disclose a method of treating bacteremia or sepsis, enhancing a mucosal response in the gastrointestinal tract or decreasing mortality of a subject having bacteremia, comprising the step of administering orally to a subject an effective amount of a lactoferrin composition comprising at least 1% to at least 50% w/w of an N-terminal lactoferrin variant to provide an improvement in the bacteremia of said subject, wherein the N-terminal lactoferrin variant has a deletion, substitution, or combination thereof, of from 1 to 16 N-terminal amino acid residues and wherein the N-terminal lactoferrin variant retains the same biological function as full length lactoferrin; and the specification indicates sepsis or bacteremia may originate anywhere in the body such as surgical wounds or decubitus ulcers (paragraphs [0003] and [0082]). Both the claims of instant application and the claims of the copending application are directed to a method of treating bacteremia or sepsis, or treating wounds such as

wounds causing bacteremia or sepsis by administering a lactoferrin composition comprising an N-terminal lactoferrin variant. Thus, claims 16-22, 26-30 and 50-51 in present application and claims 1, 7, 14, 17-19, 26-32 and 38-40 in the copending application are obvious variations of a method of treating bacteremia or sepsis, or wounds causing bacteremia or sepsis by administering a lactoferrin composition comprising an N-terminal lactoferrin variant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner

CHIH-MIN KAM
PRIMARY EXAMINER

CMK
December 4, 2006